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ETLI.P-002-US
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Robert L. Jaffe		
Serial No.:	09/086,138	Examiner:	R. Gitomer
Filed:	May 28, 1998	Art Unit:	1623
For:	DETERMINATION OF CYTOTOXIC SUBSTANCES IN WHOLE EFFLUENT SAMPLES		

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICIAL ACTION

Sir:

This is in response to the Official Action mailed April 28, 2003 for the above-captioned application. Reconsideration of the Application in view of the remarks herein is respectfully requested.

In the Decision on Appeal in this case, the Board expressed concern about the definition of whole effluent sample both within the claims, and as it was being applied by the Examiner. To facilitate clarification on this issue, claim 1 was previously amended to specify that the aliquot of the whole effluent sample which is added to the growing culture of flagellates contains "all of the potentially cytotoxic substances of the original sample obtained such that a

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I hereby certify that this paper and any attachments named herein are being deposited with the US Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 21, 2003.

Marina T Larson

Marina T. Larson, PTO Reg. No. 32,038

July 21, 2003
Date of Signature

measure of the toxicity of any combination of potentially cytotoxic substances can be obtained." This language is consistent with the art-recognized definition of whole effluent tests (WET tests) described in previously submitted papers, as well as with the specification on Page 4, line 4 et seq.

The Examiner has asserted that this amendment represents new matter. Applicants respectfully disagree. The language inserted in the claim does nothing more than expand the term "whole effluent test" in a manner consistent with manner in which the term is used in the art. Furthermore, the specification, on Page 4, lines 5-8 defines whole effluent toxicity as "toxicity of the combination of chemical compounds, both organic and inorganic which may be present in an effluent sample, and for the determination of component toxicity associated with dissolved and particular materials." This clearly indicates that the test is one which permits determination of "a measure of the toxicity of any combination of potentially cytotoxic substances" as now set forth in the claim. Thus, the Examiner's assertion that this phrase is new matter is in error.

The Examiner also rejected claims 1 and 2 under 35 USC § 102(b) as anticipated by Jaffe, US Patent No. 5,387,508). The Examiner states that "various types of whole effluent samples are taught" in this reference, but does not provide the Applicant with any explanation of what his current understanding of whole effluent sample is, or how the examples of the '508 patent could be deemed to meet this limitation. It is noted that in the prosecution prior to the Appeal, Applicants repeatedly requested the Examiner to explain how any of the examples in the '508 patent could be considered whole effluent samples, and requested an explanation of the meaning being given to this term by the Examiner. The Examiner did not do so then. which led to an Appeal which effectively wasted the time of everyone involved, including the Board of Appeals, because the record was not complete. The Board of Appeals even observed that "it is unclear how the Examiner interprets this phrase." (Decision, Page 4). Applicant is therefore puzzled by the short shrift the Examiner has given to this issue, providing even less detail than in the prior Official Actions which were vacated by the Board of Appeals.

The Examiner reinstated the vacated rejection of claims 3-15 under 35 USC § 103 as obvious over Jaffe '508. Again, Applicant might have thought it reasonable that the Examiner would offer new arguments, consistent both with the appeal process and the amendment after appeal which was filed. Instead, the Examiner simply repeats language concerning the requirement for looking at the claim as it reads, and not importing limitations from the specification, but does not seem to have followed his own admonitions. For example, on Page 6 of the Official Action the Examiner states that "it is noted in present claim 1(a) the step is 'obtaining a sample for testing suspected of containing a plurality of potentially cytotoxic substances' is not limited to any particular type of sample." Applicant points out that claim 1(a) has been amended and now reads "obtaining a liquid whole effluent sample for testing." Thus the Examiner's argument is simply wrong.

Similarly, in other comments which the Examiner has reproduced from prior papers without addressing either the subsequent amendment or the decision of the Board of Appeals, the Examiner states that the whole effluent sample is found in Example 5 of the '508 patent which tests fumes. The fumes are also not a liquid sample and thus do not meet the limitations of amended claim 1. Furthermore, the fumes in Example 5 are not tested directly nor is the testing of the complete combination of materials present in the fumes as they are emitted into the environment. The fumes are passed through a liquid reservoir. Those components which are soluble in the liquid are preferentially captured, while those components which are insoluble in the liquid may not be captured at all. There is no reasonable way in which a person skilled in the art could interpret this as a whole effluent sample and Applicant has submitted a declaration to that effect. At the very least, if the Examiner is contesting this declaration, he is obligated to state facts, not mere conclusions, which would justify his position. This he has not done.

Thus, the rejection of the claims on the art does not address the claims as amended. Applicant is entitled to a fair consideration of the application and the amended claims, not simply a reprinting of the prior rejection from the word processor. Accordingly, if the

application is not allowed, Applicant requests and demands that the Examiner set forth the reasons for his position fully, in a non-final action.

The Examiner also rejected claims 1-15 under 35 USC § 112, second paragraph, stating that claim 1, as amended, is indefinite. The Examiner states that the phrase "such that a measure of the toxicity of any combination of potentially cytotoxic substances can be obtained" is indefinite because (1) "how the substances are potentially toxic to what is not seen" and (2) "can be obtained" does not specify how it can be obtained nor from what." To the extent that these statements can be understood at all, Applicant traverses the rejection.

The measure of compliance with 35 USC § 112, second paragraph, is whether a person skilled in the art, having read the specification, can understand the scope of the claim. The measure is not whether the examiner can pluck selected words from the context of the claim and assert some lack of clarity for these words once removed from context.

It is noted the phrase "potentially cytotoxic substances" appears in part (a) and twice in part (b) of claim 1, yet the Examiner objects to the phrase only in the third instance. As is apparent from the specification, there are substances which are toxic only when present in combination with other substances. There are other substances which are toxic only when present at sufficiently high levels. These substances in the sample are referred to as "potentially cytotoxic substances" because the test is performed on samples to see if they are actually cytotoxic. As to the what the samples are toxic too, that it quite evident from both the language of the claim (cytotoxic) and the specification -- they are potentially toxic to living cells with which they may come in contact. As to the phrase "can be obtained" this is part of a complete phrase defining the nature of the aliquot tested which reads "said aliquot containing all of the potentially cytotoxic substances of the original sample obtained such that a measure of the toxicity of any combination of potentially cytotoxic substances can be obtained." The rest of the claim answers the question of how the sample is evaluated. For these reasons, Applicant submits that the rejection under § 112, second paragraph, should be withdrawn.

In view of the foregoing, Applicant submits that this application is form for allowance.

Respectfully submitted,

Marina T. Larson
Pat. Off. Reg. No. 32,038

Attorney for Applicant
(970) 468-6600